

Appendix 6:

## "Dear Speaker" letter



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration  
1350 Piccard Drive  
Rockville, MD 20850

Ms. Chris Tirpak, MA, MPA  
C.S.I. Program Manager  
US-EPA  
Chemical Control Division (MC 7405)  
401 M Street, SW  
Washington, DC 20460

Dear Ms. Tirpak:

We are delighted you have agreed to speak at the seminar sponsored by the Office of Surveillance and Biometrics (OSB), Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA). As you know, the seminar scheduled for October 28, 1998 will address Outside Leveraging. The purpose of the seminar is for our employees to hear about creative successes and lessons learned by some of the pioneers this kind of activity and then to apply this knowledge and explore the possibilities for outside leveraging in our own office.

**Outside Leveraging** is the term we have adopted to describe the creation of relationships and/or formal agreements with others outside the Center for Devices and Radiological Health (CDRH) to obtain services/support for little or no monetary exchange. These services will support our mission of postmarket surveillance and statistical support for regulation of medical devices to insure they are safe and effective.

As federal budgets get smaller and our public health missions increase in size and complexity, we agree government must become more creative and discover new methods that allow us to operate efficiently and still meet our responsibility to protect the health of the American public.

Our partnerships with academia, professional and standard setting organizations, other regulators, the health care community, trade groups, consumer advocates, private industry and others will enable us to multiply the positive results of joint efforts. Such agreements

will also aid us in focusing our very limited government resources in the narrow areas that are exclusively government responsibility.

Our Project Manager, Pat Spitzig, will be happy to provide information regarding the context of the seminar. She can be reached by calling 301-594-2483. Midge Brier is available to provide information regarding logistics and media arrangements. She can be reached at 301- 827-3620. Thank you in advance for your willingness to share your wisdom with us. We are very grateful for your help and support.

Sincerely,

Dr. Larry G. Kessler, Director  
Office of Surveillance and Biometrics  
Center for Devices and Radiological Health

Encl. - 4  
CDRH Mission Statement  
OSB Annual Report  
OSB Mission Statement  
OSB Vision Statement